

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
29 April 2004 (29.04.2004)

PCT

(10) International Publication Number
WO 2004/035115 A1

(51) International Patent Classification⁷: **A61M 5/142**

Reflections Dr., Dublin, OH 43017 (US). NELSON, Steven, R.; 2039 Newmarket Ct., Grove City, OH 43123 (US). FORTNEY, Clark, E.; 899 Trifecta Court, Gahanna, OH 43230 (US).

(21) International Application Number:
PCT/US2003/031698

(22) International Filing Date: 7 October 2003 (07.10.2003)

(74) Agents: CRABB, Michael, R. et al.; Dept 377/AP6A-1, 100 Abbott Park Road, Abbott Park, IL 60064-6008 (US).

(25) Filing Language: English

(81) Designated States (*national*): CA, JP, MX, NO.

(26) Publication Language: English

(84) Designated States (*regional*): European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR).

(30) Priority Data:
60/418,914 16 October 2002 (16.10.2002) US
60/418,986 16 October 2002 (16.10.2002) US
10/624,667 22 July 2003 (22.07.2003) US
10/624,578 22 July 2003 (22.07.2003) US

Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

(71) Applicant: ABBOTT LABORATORIES [US/US];
D-377 AP6A-1, 100 Abbott Park Road, Abbott Park, IL
60064-6008 (US).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(72) Inventors: BOUTON, Chad, E.; 312 Pecan Ct.,
Delaware, OH 43015 (US). RADCLIFF, Dale, M.; 6600

(54) Title: METHOD FOR DISCRIMINATING BETWEEN OPERATING CONDITIONS IN MEDICAL PUMP

(57) Abstract: A method is disclosed for determining the operating condition of a medical pump based on data derived from a pressure sensor and a position sensor. The pressure sensor generates pressure data by sensing the force on the pumping element. The position sensor generates position data by tracking the pumping cycle and determining the position of the pumping element. The pump pressure data and pump position data are processed and the calculated results compared with a pre-determined threshold value to determine the operating condition of the pump. The three main types of operating conditions of concern are the following: normal condition, where liquid is present and no leaks exist in pumping chamber; leak condition, where liquid is present but a leak exists in the pumping chamber; and air stroke condition, where the chamber contains some air.

WO 2004/035115 A1

METHOD FOR DISCRIMINATING BETWEEN OPERATING
CONDITIONS IN MEDICAL PUMP

5 CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional Application No. 60/418,914, filed on October 16, 2002, and of U.S. Provisional Application No. 60/418,986, filed on October 16, 2002.

10

BACKGROUND OF THE INVENTION

The present invention relates to a method of determining the operating condition of a medical pump'. More particularly, this invention relates to a method of determining fluid status in positive displacement fluid pumping devices for the delivery of fluids to a patient.

Modern medical care often involves the use of medical pump devices to deliver fluids and/or fluid medicine to patients. Medical pumps permit the controlled delivery of fluids to a patient, and such pumps have largely replaced gravity flow systems, primarily due to the pump's much greater accuracy in delivery rates and dosages, and due to the possibility for flexible yet controlled delivery schedules. Of the modern medical pumps, those incorporating a diaphragm or pump cassette are often preferred because they provide a more accurate controlled rate and volume than do other types of pumps.

A typical positive displacement pump system includes a pump device driver and a disposable cassette. The disposable cassette, which is adapted to be used only for a single patient and for one fluid delivery cycle, is typically a small plastic unit having an inlet and an outlet respectively connected through flexible tubing to the fluid supply

container and to the patient receiving the fluid. The cassette includes a pumping chamber, with the flow of fluid through the chamber being controlled by a plunger or piston activated in a controlled manner by the device driver.

5 For example, the cassette chamber may have one wall formed by a flexible diaphragm which is reciprocated by the plunger and the driver to cause fluid to flow. The pump driver device includes the plunger or piston for controlling the flow of fluid into and out of the pumping chamber in the
10 cassette, and it also includes control mechanisms to assure that the fluid is delivered to the patient at a pre-set rate, in a pre-determined manner, and only for a particular pre-selected time or total dosage.

The fluid enters the cassette through an inlet and is
15 forced through an outlet under pressure. The fluid is delivered to the outlet when the pump plunger forces the membrane into the pumping chamber to displace the fluid. During the intake stroke the pump plunger draws back, the membrane covering the pumping chamber pulls back from its
20 prior fully displaced configuration, and the fluid is then drawn through the open inlet and into the pumping chamber. In a pumping stroke, the pump plunger forces the membrane back into the pumping chamber to force the fluid contained therein through the outlet. Thus, the fluid flows from the cassette
25 in a series of spaced-apart pulses rather than in a continuous flow.

One of the requirements for a medical pump is that it is able to detect when it is operating under certain abnormal situations and to alert the user to these problems.

30 Specifically, the pump should detect when flow of fluid is blocked, there is no fluid in the line, there is no cassette in the pump, if the pump has primed correctly, and if the valves in the pump are sealing properly.

Previous pumps that could supply all this information used at least two sensors associated with the pump chamber or tubes to provide input to the control system. The use of multiple sensors requires more physical space on the pump and potentially results in a higher unit manufacturing cost.

It is therefore a principal object of this invention to provide methods of using single pressure sensor to discriminate between operating conditions in a medical pump.

These and other objects will be apparent to those skilled in the art.

SUMMARY OF THE INVENTION

A method is disclosed for determining the operating condition of a medical pump based on data derived from a pressure sensor and a position sensor. The pressure sensor generates pressure data by sensing the force on the pumping element. The position sensor generates position data by tracking the pumping cycle and determining the position of the pumping element. The pump pressure data and pump position data are processed. The processed data is compared with a pre-determined threshold value to determine the operating condition of the pump. The three main types of operating conditions of concern are the following: normal condition, where liquid is present and no leaks exist in pumping chamber; leak condition, where liquid is present but a leak exists in the pumping chamber; and air stroke condition, where the chamber contains some air.

DESCRIPTION OF THE DRAWINGS

Fig. 1 is a graph showing data from a pump cycle illustrating normal, leak and air stroke conditions;

Fig. 2 is an enlarged view of the graph of Fig. 1, taken along line 2-2, showing data from a pump cycle illustrating normal, leak and air stroke conditions;

Fig. 3 is a graph showing data from a pump cycle illustrating normal stroke conditions with various back-pressure levels;

Fig. 4 is a flow chart illustrating one embodiment of determining the operating condition of a medical pump according to the present invention;

Fig. 5 is a flow chart illustrating another embodiment of determining the operating condition of a medical pump according to the present invention;

Fig. 6 is a flow chart illustrating another embodiment of determining the operating condition of a medical pump according to the present invention; and

Fig. 7 is a schematic diagram of the cassette pump, illustrating the functional components of the pump and the cassette.

DETAILED DESCRIPTION OF THE EMBODIMENTS OF THE INVENTION

The present invention will be described as it applies to its preferred embodiment. It is not intended that the present invention be limited to the preferred embodiment. It is intended that the invention cover all modifications and alternatives that may be included within the scope of the invention as defined by the claims that follow.

It will be understood by one of ordinary skill in the art that the term medical pump as used herein includes but is not limited to enteral pumps, parenteral infusion pumps, ambulatory pumps, or any positive displacement fluid pumping device for the delivery of fluids to a patient.

Fig. 7 is a schematic diagram illustrating the functional components of a medical pump 10, which is used in connection

with a disposable cassette 12 for delivering a fluid to a patient. The medical pump 10 and cassette 12 are shown with several components for implementing the present invention. Those of ordinary skill in the art will appreciate that the pump 10 and cassette 12 include many more components than those shown in Fig. 7. However, it is not necessary that all these components be shown in order to disclose an illustrative embodiment for practicing the present invention.

Details of pump 10 and cassette 12 that are not discussed below can be determined by reference to commonly assigned and co-pending non-provisional application entitled MEANS FOR USING SINGLE FORCE SENSOR TO SUPPLY ALL NECESSARY INFORMATION FOR DETERMINATION OF STATUS OF MEDICAL PUMP, which claims priority from provisional applications U.S. Ser. No.

60/418,986 and 60/418,914, the disclosure and drawings of which are hereby specifically incorporated herein by reference in its entirety. This disclosure describes in detail means of using a single pressure sensor and a single position sensor to supply all necessary information to determine the status of a medical pump. The disclosures and drawings of the provisional applications U.S. Ser. No. 60/418,986 and 60/418,914 are also specifically incorporated herein by reference in their entirety. Commonly assigned and co-pending non-provisional application U.S. Serial No. 29/166,389 entitled PUMP CASSETTE discloses the particular cassette 12 described below. Pump cassettes and cassette pumps in general are well known in the art of medical fluid delivery, as evidenced by commonly assigned U.S. Patent Nos. 4,818,186; 4,842,584; and 5,000,664, the entire disclosure and drawings of which are hereby specifically incorporated herein by reference.

Cassette 12 includes a housing 14 on which is disposed an inlet port 16 for accepting the fluid flowing from an IV bag or other fluid container (not shown). Similarly, fluid lines

(not shown) couple an outlet port 18 on housing 14 to the body of a patient.

A pumping chamber 20 is connected in fluid flow communication between the inlet port 16 and the outlet port 18. The pumping chamber 20 operates to meter fluid through the cassette 12.

An inlet valve 22 resides between inlet port 16 and the pumping chamber 20. Inlet valve 22 operates to physically open and close the fluid communication between inlet port 16 and pumping chamber 20.

Similarly, an outlet valve 24 resides between the pumping chamber 20 and outlet port 18. Outlet valve 24 operates to physically open and close the fluid communication between pumping chamber 20 and outlet port 18. The pumping chamber 20, inlet valve 22, and outlet valve 24 are all operatively associated with the pump 10 to control the flow of fluid through the cassette 12.

A processing unit 26 with a testing timer 27 is included in pump 10 and performs various operations described in greater detail below. A display/input device 28 communicates with the processing unit 26 and allows the user to receive output from processing unit 26 and/or input into the processing unit 26. Those of ordinary skill in the art will appreciate that display/input device 28 may be provided as a separate display device and a separate input device.

A memory 30 communicates with the processing unit 26 and stores code and data necessary for the processing unit 26 to calculate and output the operating conditions of pump 10. More specifically, the memory 30 stores an algorithm code 32 formed in accordance with the present invention for processing data to determine the operating condition of the pump 10.

An electric motor 34 is controlled by processing unit 26 is energized by a power supply (not shown) to serve as a prime mover for rotatably driving a shaft 36.

5 A pumping element 38 is operatively associated with the shaft 36. When energized, the pumping element 38 reciprocates back and forth to periodically down-stroke, causing pumping element 38 to press on pumping chamber 20, driving fluid through cassette 12. On an up-stroke, pumping element 38 releases pressure from pumping chamber 20 and thereby drawing
10 fluid from inlet port 16 into pumping chamber 20.

An inlet control element 40 is operatively associated with the shaft 36. When energized, inlet control element 40 reciprocates back and forth to periodically down-stroke, causing inlet control element 40 to press on inlet valve 22,
15 closing pumping chamber 20 to fluid influx. On an up-stroke, inlet control element 40 releases pressure from inlet valve 22 and thereby allows the flow of fluid from inlet port 16 into pumping chamber 20.

An outlet control element 42 is operatively associated
20 with the shaft 36. When energized, outlet control element 42 reciprocates back and forth to periodically down-stroke, causing outlet control element 42 to press on outlet valve 24, closing pumping chamber 20 to fluid efflux. On an up-stroke, outlet control element 42 releases pressure from outlet valve
25 24 and thereby allows the flow of fluid from pumping chamber 20 to outlet port 18. Thus the open or closed state of pumping chamber 20 is controlled by the positioning and movement of inlet and outlet control elements 40 and 42.

A pressure sensor 44 is operatively associated with the
30 pumping element 38. The pressure sensor 44 senses the force on pumping element 38 and generates a pressure signal based on this force. The pressure sensor 44 communicates with the processing unit 26, sending the pressure signal to the

processing unit 26 for use in determining operating conditions of pump 10.

One of ordinary skill in the art will appreciate that the pressure sensor 44 may be a force transducer or any other device that can operatively sense the pressure brought to bear on the pumping chamber 20 by pumping element 38.

A position sensor 46 tracks the pumping cycle of pump 10 by determining the position of the pumping element 38. The position sensor 46 can be operatively associated with the shaft 36, a cam or camshaft 76 attached to the shaft 36, or the pumping element 38 itself. The position sensor 46 generates a position signal by directly or indirectly detecting the position of the pumping element 38. For instance, in one embodiment the position sensor 46 is a Hall Effect sensor having a magnet (not shown) in relational contact with shaft 36. The rotational position of shaft 36 can be monitored to indirectly detecting the position of the pumping element 38. The position sensor 46 communicates with the processing unit 26, sending the position signal to the processing unit 26 for use in determining operating conditions of pump 10. One of ordinary skill in the art will appreciate that the position sensor 46 as used herein includes but is not limited to mechanical indicators such as pivoting dial indicators, electronic switches, Hall Effect sensors, and optical based position detectors.

In operation, at the beginning of a pumping cycle, outlet control element 42 operates to close outlet valve 24 so that there is no fluid communication between pumping chamber 20 and outlet port 18. Inlet valve 22 is opened to permit pumping chamber 20 to be in fluid communication with inlet port 16. In the next phase of the pumping cycle, inlet control element 40 operates to close inlet valve 22, thereby closing fluid communication between inlet port 16 and pumping chamber 20.

Outlet valve 24 continues to remain closed. Next, pumping element 38 begins a down-stroke movement which presses pumping element 38 against pumping chamber 20, causing pumping chamber 20 to compress, thereby increasing the pressure within pumping chamber 20. Pressure sensor 44 reads and transmits this pressure data to processing unit 26. Under normal conditions pumping chamber 20 is compressed sufficiently and a desired pressure profile is generated. At a given position of shaft 36 or point in the pumping cycle, the outlet control element 42 operates to open outlet valve 24 so that fluid flows from pumping chamber 20 to outlet port 18. The pump cycle then repeats.

The processing unit 26 retrieves the operating condition algorithm 32 from memory 30 and applies it to the pressure and position data received from this pump cycle. The pump pressure data and pump position data are processed. The processed data is compared with a pre-determined threshold value to determine the operating condition of the pump. The three main types of operating conditions of concern are the following: normal condition, where liquid is present and no leaks exist in pumping chamber; leak condition, where liquid is present but a leak exists in the pumping chamber 20 (including at the inlet valve 22 or outlet valve 24); and air stroke condition, where the chamber contains some air. Once the operating condition is determined, the processing unit 26 outputs the operating condition display 28 and/or uses the determined operating condition to adjust operation of the pump.

One of ordinary skill in the art will understand that the threshold values for any of the algorithms disclosed herein are predetermined empirically from experimental data, and will vary from pump model to pump model.

Referring to Fig. 1, the position sensor 46 is used to trigger a capture event where pressure sensor 44 data is captured for processing and operating condition discrimination. Fig. 1 shows time plots of the pressure and position signals taken with a prototype unit in the laboratory. The position signals are digital in nature and take on values near 3 or 0 V. The remaining analog signals that rise and fall more gradually are the signals that represent the pressure sensor 44 measurements. There is one pressure sensor 44 in the system and the four analog signals shown represent four different example operating conditions that have been superimposed onto the same plot. Each will be used to explain the operation of the signal processing algorithms to be disclosed.

When large amounts of data under various experimental conditions were collected, certain observations were made immediately. As shown in the example set of data shown in FIG. 1, the initial time region between -0.4s and 0s did not seem to offer opportunities for signal discrimination. Furthermore, other regions beyond 0.2s also did not seem to offer signal differences that corresponded with the operating conditions of interest. Specifically, in these regions of non-interest, the back-pressure and other elements in the system seemed to dominate the pressure signal characteristics. In a region of interest, marked by line 2-2, the system is indeed operating with the pumping chamber 20 closed such that the pressure sensor 44 is detecting a building pressure during the pumping stroke. This allows unique conditions under which it may be possible to discriminate between normal, leaky, and air-filled pumping conditions.

Referring to Figs. 1 and 2, the data for the region of interest marked by line 2-2 of Fig. 1 is shown with greater detail. Pump cycle data was collected in the laboratory by

subjecting a prototype pump to a wide variety of operating and environmental conditions to analyze the region of interest more closely. To develop effective and robust algorithms, it was important to analyze time shifting, bias shifts or offsets, and other variations that could occur. The four digital position signals are numbered as A and the four pressure signals are numbered B-E. The example pressure signals B-E correspond to the three previously mentioned operating condition types (Normal, Leak, and Air Stroke), and in addition a back-pressure in the system may be present. The numbered cases in the figure are as follows:

B: Normal type, no back-pressure;

C: Normal type, relatively high back-pressure present;

D: Leak type, low back-pressure; and

E: Air Stroke, low back-pressure.

Those of ordinary skill in the art will recognize that the magnitude, timing, and shape of the pressure signals may vary somewhat depending on the source or location of the leak(s), amount of air, or amount of back-pressure. For example, there are at least two more cases or combinations not shown in Fig. 2. These cases are leak type with high back-pressure and air stroke with high back-pressure.

Data for many other condition combinations were collected and analyzed, and the region of interest (shown in Fig. 1 at line 2-2 and in Fig. 2) remained the most viable one. In particular, data captured prior to a next rising edge G of the position sensor 46 proved to be an effective data set. This is due to the widely varying and uncorrelated effects that the back-pressure in the system that occurs after this rising edge G has on the pressure signal. Therefore the specific region of interest (at line 2-2) occurs between the second falling edge F of the position sensor 46 that occurs in the complete

pump cycle and a time point before the next rising edge G of this position signal.

A number of algorithms were considered and tested prior to the development of the final preferred set. Among these
5 included a simple threshold method and a method in which the falling edge of the pressure signal was analyzed (falling edge method).

The simple threshold method involved comparing the pressure signal against a predetermined threshold. However,
10 varying signal offsets in the system reduced the performance of this method, making this method ineffective in discriminating between the operating conditions.

Referring to Fig. 3, in the falling edge method, the time derivative (or slope) of the data falling within the region of
15 interest (at line 2-2 in Fig. 1) was calculated and compared to a negative threshold. With this approach a falling edge, usually typifying a normal stroke, would result in a time derivative calculation that would exceed the negative threshold. Air strokes and certain leak conditions often did
20 not contain this falling edge characteristic and would not exceed the set threshold. However, a normal stroke with a significant back-pressure often did not have this falling edge. This can be seen in Fig. 3, where some normal type strokes do have the falling edges when the back-pressure
25 levels are low and some do not when the back-pressure is high. This condition therefore made the falling edge method ineffective in discriminating between the operating conditions.

Other approaches and variations in the same general
30 spirit were considered, but only the preferred approaches below will be described in detail in this disclosure. Three main embodiments of the preferred algorithms were developed and are listed as follows:

Class 1: Delayed Threshold Algorithm;

Class 2: Weighted Integration Algorithm; and

Class 3: Integrated Split Derivative Algorithm.

There are a variety of possible variations on each class
5 of algorithm. These variations include varying the technique
of weighting, disabling the weighting, position of anchor, and
sequence order in which data is analyzed. The Class 1 delayed
threshold algorithm is the preferred embodiment. However, the
other algorithms to be described can perform equally as well
10 under certain conditions. Therefore, all algorithms are
equally important and will be discussed in equivalent detail.

Referring to Fig. 4, the overall operation of the Class 1
algorithm 110 is shown in flowchart form. The Class 1
algorithm 110 begins at start block 112. A decision block 114
15 monitors the pump cycle through position signal A to determine
when a region of interest is occurring. In this example, the
region of interest is specified as starting when the second
falling edge F of the position signal A is detected in each
new pump cycle. When the second falling edge F is detected at
20 decision block 114, the Class 1 algorithm 110 proceeds to
block 116. Block 116 starts the testing timer 27 for a pre-
determined test time Td. Then a block 118 acquires a
plurality of pressure reference values at some pre-determined
sampling rate during a first portion of test time, and once
25 the first Na pressure reference values have been acquired a
pressure anchor value is calculated and stored by averaging
these pressure reference values. This anchor is stored and
will be used in later calculations.

Anchoring is a technique used in this and the other
30 algorithms as a process that removes the overall offset
variation observed in the pressure signal from one pump cycle
to the next and between each physical pump unit. This process
involves averaging a number of the initial data points in the

data set of interest and subtracting this averaged valued from all subsequent data points in the set.

A block 120 acquires a pressure data value and then calculates and stores a resultant value by subtracting the anchor value from the data value. A buffer is created and maintained for storing the last Nb resultant value samples (or data points). This buffer may be a circular buffer to improved processing efficiency. A decision block 122 shows just such a circular buffer, and repeats the steps of acquiring the pressure data value and calculating and storing the resultant value until the pre-determined test time Td has expired. Thus, as each new pressure data value is acquired the buffer is updated, until the pre-determined value of time Td has elapsed. If time Td has elapsed, then the data acquisition is complete and the final processing occurs.

During the final processing, a block 124 calculates a test value by averaging the resultant values, and compares this test value with a pre-determined threshold value to determine the operating condition of the pump. Thus, in the last step, the algorithm 110 averages the Nb data points in the storage buffer and compares this averaged value to a set of predetermined thresholds to determine the operating condition of the pump (i.e. normal, leak, or air stroke).

Referring to Fig. 5, the overall operation of the Class 2 weighted integration algorithm 130 is shown in flowchart form. This algorithm begins the same way as the Class 1 algorithm 130 begins, but the difference of operation lies in the update buffer and final steps.

The Class 2 algorithm 130 begins at start block 132. A decision block 134 monitors the pump cycle through position signal A to determine when a region of interest is occurring. In this example, the region of interest is specified as starting when the second falling edge F of the position signal

A is detected in each new pump cycle. When the second falling edge F is detected at decision block 134, the Class 2 algorithm 130 proceeds to block 136. Block 136 starts the testing timer 27 for a pre-determined test time T_d . Then a block 138 acquires a plurality of pressure reference values at some pre-determined sampling rate during a first portion of test time, and once the first N_a pressure reference values have been acquired a pressure anchor value is calculated and stored by averaging these pressure reference values. This anchor is stored and will be used in later calculations.

A block 140 makes the core calculations of algorithm 130 during the buffer update to calculate an integration term. The following equation describes the integration term used in block 140:

$$I_k = I_{k-1} + (d_k - A) W(t)$$

Where I_k represents the integration term, I_{k-1} represents the prior integration term, d_k represents the newly acquired pressure data value, A represents the anchor value, and $W(t)$ represents the weighting value which is a function of the time (or position) at which the new pressure data value was acquired. The function $W(t)$ can be linear, polynomial, or any other function of time to allow the emphasis and de-emphasis of various regions in the data set.

The block 140 sets a first prior integration term I_{k-1} of zero when the algorithm first begins during each new pump cycle. The block 140 acquires a pressure data value d_k and then calculates and stores a new integration term I_k by subtracting the anchor value A from the data value d_k to obtain a resultant, multiplying the resultant by a weighting value $W(t)$ to obtain a product, and adding the product to the prior integration term I_{k-1} .

A decision block 142 repeats the steps of acquiring the pressure data value d_k and calculating and storing the new

integration term I_k until the pre-determined test time T_d has expired. Thus, as each new pressure data value d_k is acquired the new integration term I_k is updated, until the pre-determined value of time T_d has elapsed. If time T_d has elapsed, then the data acquisition is complete and the final processing occurs.

During the final processing, a block 144 compares the integration term I_k with a pre-determined threshold value to determine the operating condition of the pump (i.e. normal, leak, or air stroke).

Referring to Fig. 6, the overall operation of the Class 3 integrated split derivative algorithm 150 is shown in flowchart form. The Class 3 algorithm 150 begins the same way Class 2 130 begins, but no anchor calculation is used, and the update buffer and final steps differ.

The Class 3 algorithm 150 begins at start block 152. A decision block 154 monitors the pump cycle through position signal A to determine when a region of interest is occurring. In this example, the region of interest is specified as starting when the second falling edge F of the position signal A is detected in each new pump cycle. When the second falling edge F is detected at decision block 154, the Class 3 algorithm 150 proceeds to block 156. Block 156 starts the testing timer 27 for a pre-determined test time T_d .

A block 158 makes the core calculations of algorithm 150 during the buffer update to calculate a figure of merit. The following equation describes the figure of merit calculation used in block 158:

$$FOM_k = FOM_{k-1} + (d_k - d_{k-q}) W(t)$$

Where FOM_k represents the figure of merit, FOM_{k-1} represents the prior figure of merit, d_k represents the newly acquired pressure data value, d_{k-q} represents any other pressure data value in the set, and $W(t)$ represents the

weighting value which is a function of the time (or position) at which the new pressure data value was acquired. The function $W(t)$ can be a linear, polynomial, or any other function of time to allow the emphasis and de-emphasis of various regions in the data set.

The block 158 sets a first prior figure of merit FOM_{K-1} of zero when the algorithm 150 first begins during each new pump cycle. The block 158 acquires the prior pressure data value d_{k-q} and the new pressure data value d_k , where the prior pressure data value d_{k-q} is any data value other than the new pressure data value. The block 158 calculates and stores a new figure of merit FOM_k by subtracting the prior pressure data value d_{k-q} from the new pressure data value d_k to obtain a resultant, multiplying the resultant by the weighting value $W(t)$ to obtain a product, and adding the product to the prior figure of merit FOM_{K-1} .

A decision block 160 repeats the steps of acquiring the new pressure data value d_k and calculating and storing the new figure of merit FOM_k until the pre-determined test time T_d has expired. Thus, as each new pressure data value d_k is acquired the new figure of merit FOM_k is updated, until the pre-determined value of time T_d has elapsed. If time T_d has elapsed, then the data acquisition is complete and the final processing occurs.

During the final processing, a block 162 compares the figure of merit FOM_k to pre-determined thresholds to determine the operating condition of the pump (i.e. normal, leak, or air stroke). For example, in one embodiment one threshold is set at 450 so that if the Figure of Merit is above 450, the pump interprets this as a normal fluid stroke; below 450, as an air stroke.

Several variations on each class of algorithms are possible which can enhance performance. These variations

include varying the trigger event, technique of weighting, disabling the weighting, position of anchor, and the sequence order in which data is analyzed.

While the trigger event in the preferred embodiment is the second falling edge F of the position sensor, the trigger event can be changed to reduce system variation sensitivity as needed. The trigger event may be, for example, the second rising edge G in the pump cycle shown in Fig. 1. Setting rising edge G as the trigger event may reduce delay between the trigger event and data collection in the Class 1 algorithm 110, for example. This is important due to the fact that the Class 1 algorithm 110 will perform more satisfactorily if the pressure signal data collected correlate to a certain desired pump position. Since there is no pump element position or speed sensing available, the timer and predicted speed is used to estimate the current position. Shortening the delay between the trigger event and key data collection will reduce the accumulating effects of speed variations in the pumping motor and estimated position error, therefore increasing the probability that the collected data corresponds to the desired and anticipated position.

Another variation involves the smoothing of the data set. It is possible to acquire all data of interest before algorithm calculations begin. In this case, the data can be smoothed prior to core calculations. This is effective when the pressure signal contains undesirable noise.

The anchor location is another variable that can be changed to enhance system performance. In Class 1 algorithm 110 and Class 2 algorithm 130 embodiments the anchor is calculated by using the first Na data points. Depending on the curvature and nature of the data set, it may be advantageous to calculate this anchor by using the data points at some other location within the data set. This may

accentuate a certain feature near the new anchor location and increase the discrimination level of the algorithm.

Whereas the invention has been shown and described in connection with the embodiments thereof, it will be understood
5 that many modifications, substitutions, and additions may be made which are within the intended broad scope of the following claims. From the foregoing, it can be seen that the present invention accomplishes at least all of the stated objectives.

10

I claim:

1. A method for determining operating conditions in a medical pump having a cassette with a pumping chamber, comprising:
5 monitoring the pump cycle with a position sensor;
closing the pumping chamber to flow during at least a portion
of the pump cycle;
pressurizing the pumping chamber and acquiring a plurality of
pressure data values from a single pressure sensor while
10 the chamber is closed; and
processing the pressure data values to determine the operating
condition of the pump.
2. The method of claim 1, wherein the operating condition
15 determined is normal type, leak type, or air stroke.
3. A method for determining operating conditions in a medical pump having a cassette with a pumping chamber, comprising:
monitoring the pump cycle with a position sensor;
20 starting a testing timer for a pre-determined test time at a
specified portion of the pump cycle;
closing the pumping chamber to flow during at least a portion
of the specified portion of the pump cycle;
acquiring a plurality of pressure reference values during a
25 first portion of test time from a single pressure sensor;
calculating and storing a pressure anchor value by averaging
the reference values;
acquiring a pressure data value from the pressure sensor;
calculating and storing a resultant value by subtracting the
30 anchor value from the data value;
repeating the steps of acquiring the pressure data value and
calculating and storing the resultant value until the
pre-determined test time has expired;

calculating a test value by averaging the resultant values;

and

comparing the test value with pre-determined threshold value
to determine the operating condition of the pump.

5

4. The method of claim 3, wherein the operating condition
determined is normal type, leak type, or air stroke.

10

5. The method of claim 3, further comprising the step of
smoothing the pressure reference values and pressure data
values prior to performance of the calculation steps.

15

6. The method of claim 3, wherein the specified portion of
the pump cycle is adjusted to reduce system variation
sensitivity.

20

7. The method of claim 3, wherein the first portion of test
time is adjusted to shorten the delay between the steps of
starting the testing timer at the specified portion of the
pump cycle and acquiring the pressure data value.

25

8. The method of claim 3, wherein the specified portion of
the pump cycle and the first portion of test time are adjusted
to vary the pressure anchor value.

9. The method of claim 3, wherein portions of the pressure
reference values and pressure data values are weighted to
adjust the emphasis of these portions.

30

10. A method for determining operating conditions in a
medical pump having a cassette with a pumping chamber,
comprising:
monitoring the pump cycle with a position sensor;

starting a testing timer for a pre-determined test time at a specified portion of the pump cycle;

closing the pumping chamber to flow during at least a portion of the specified portion of the pump cycle;

5 acquiring a plurality of pressure reference values during a first portion of test time from a single pressure sensor; calculating and storing a pressure anchor value by averaging the reference values;

setting a first prior integration term of zero;

10 acquiring a pressure data value from the pressure sensor; calculating and storing a new integration term by subtracting the anchor value from the data value to obtain a resultant, multiplying the resultant by a weighting value to obtain a product, and adding the product to the prior
15 integration term;

repeating the steps of acquiring the pressure data value and calculating and storing the new integration term until the pre-determined test time has expired; and

20 comparing the new integration term with a pre-determined threshold value to determine the operating condition of the pump.

11. The method of claim 10, wherein the operating condition determined is normal type, leak type, or air stroke.

25

12. The method of claim 10, further comprising the step of smoothing the pressure reference values and pressure data values prior to performance of the calculation steps.

30 13. The method of claim 10, wherein the specified portion of the pump cycle is adjusted to reduce system variation sensitivity.

14. The method of claim 10, wherein the first portion of test time is adjusted to shorten the delay between the steps of starting the testing timer at the specified portion of the pump cycle and acquiring the pressure data value.

5

15. The method of claim 10, wherein the specified portion of the pump cycle and the first portion of test time are adjusted to vary the pressure anchor value.

10 16. The method of claim 10, wherein portions of the pressure reference values and pressure data values are weighted to adjust the emphasis of these portions.

17. A method for determining operating conditions in a,
15 medical pump having a cassette with a pumping chamber,
comprising:
monitoring the pump cycle with a position sensor;
starting a testing timer for a pre-determined test time at a
specified portion of the pump cycle;
20 closing the pumping chamber to flow during at least a portion
of the specified portion of the pump cycle;
setting a first prior figure of merit value of zero;
acquiring a prior pressure data value from a single pressure
sensor;
25 acquiring a new pressure data value from the pressure sensor,
where the prior pressure data value is any data value
other than the new pressure data value;
calculating and storing a new figure of merit value by
subtracting the prior pressure data value from the new
30 pressure data value to obtain a resultant, multiplying
the resultant by a weighting value to obtain a product,
and adding the product to the prior figure of merit;

repeating the steps of acquiring the new pressure data value
and calculating and storing the new figure of merit value
until the pre-determined test time has expired; and
comparing the figure of merit value with a pre-determined
5 threshold value to determine the operating condition of
the pump.

18. The method of claim 17, wherein the operating condition
determined is normal type, leak type, or air stroke.

19. The method of claim 17, further comprising the step of
smoothing the pressure reference values and pressure data
values prior to performance of the calculation steps.

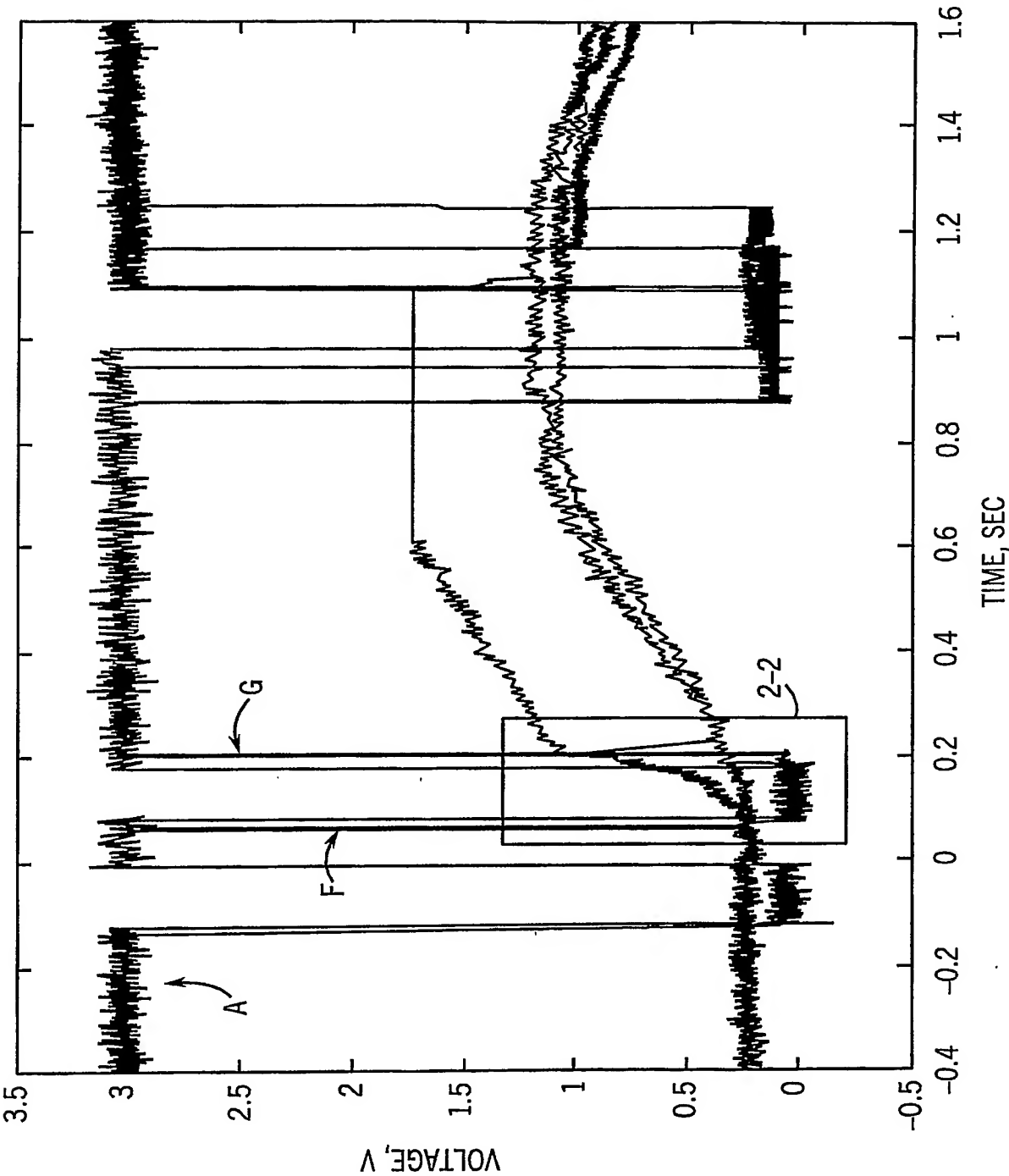
20. The method of claim 17, wherein the specified portion of
the pump cycle is adjusted to reduce system variation
sensitivity.

21. The method of claim 17, wherein the first portion of test
time is adjusted to shorten the delay between the steps of
starting the testing timer at the specified portion of the
pump cycle and acquiring the pressure data value.

22. The method of claim 17, wherein the specified portion of
the pump cycle and the first portion of test time are adjusted
to vary the pressure anchor value.

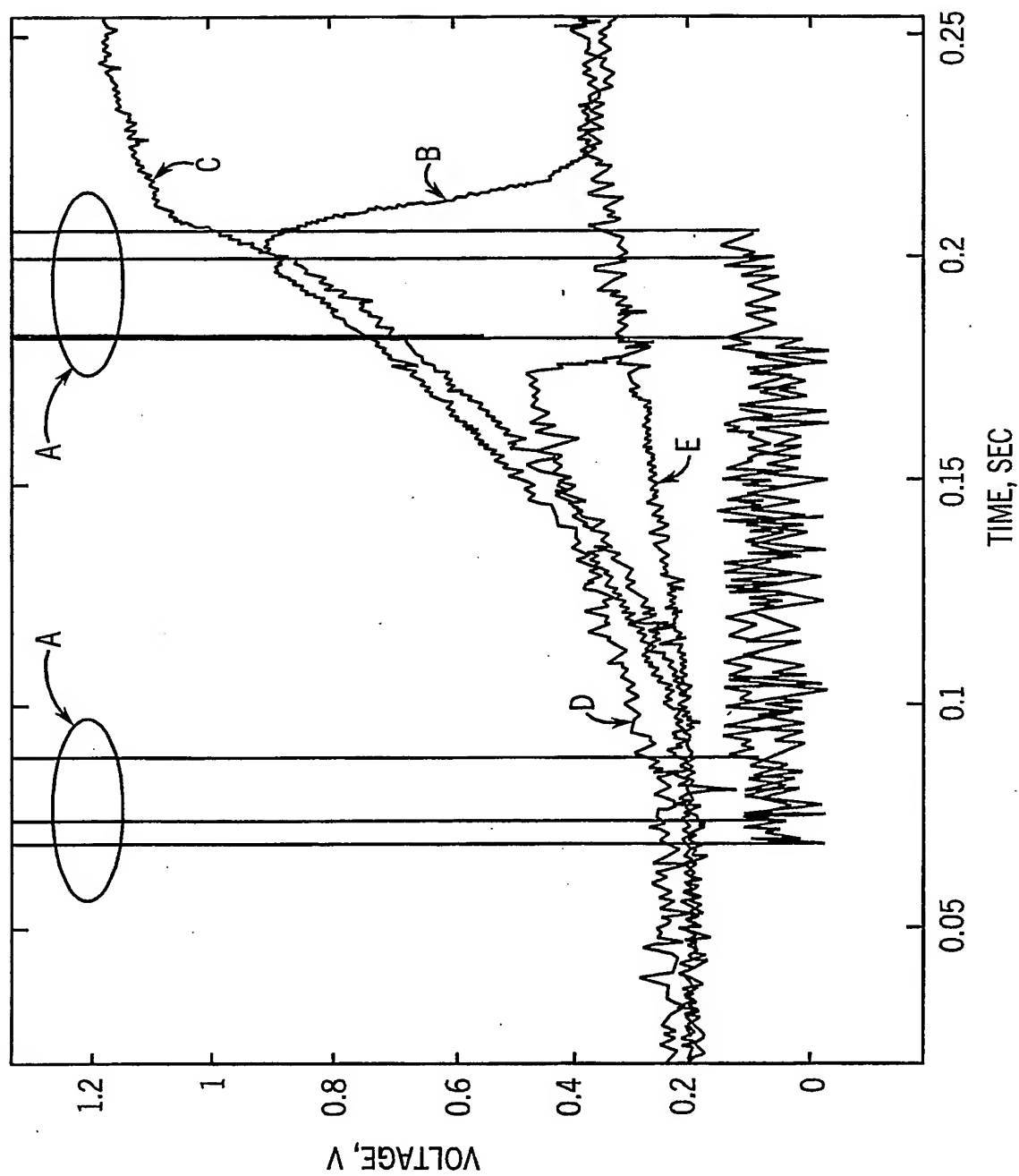
23. The method of claim 17, wherein portions of the pressure
reference values and pressure data values are weighted to
adjust the emphasis of these portions.

FIG. 1



2 / 7

FIG. 2



3 / 7

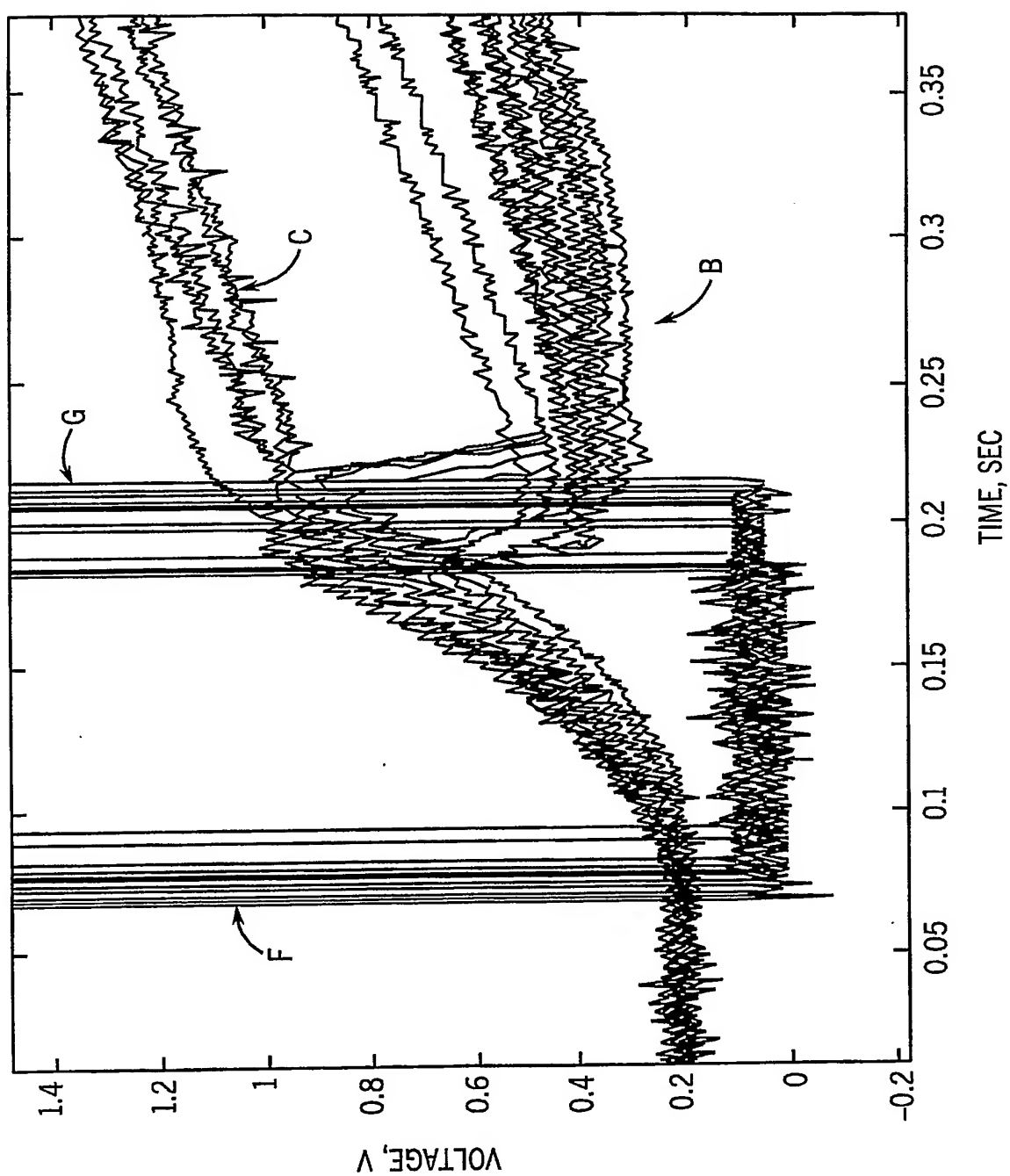


FIG. 3

4 / 7

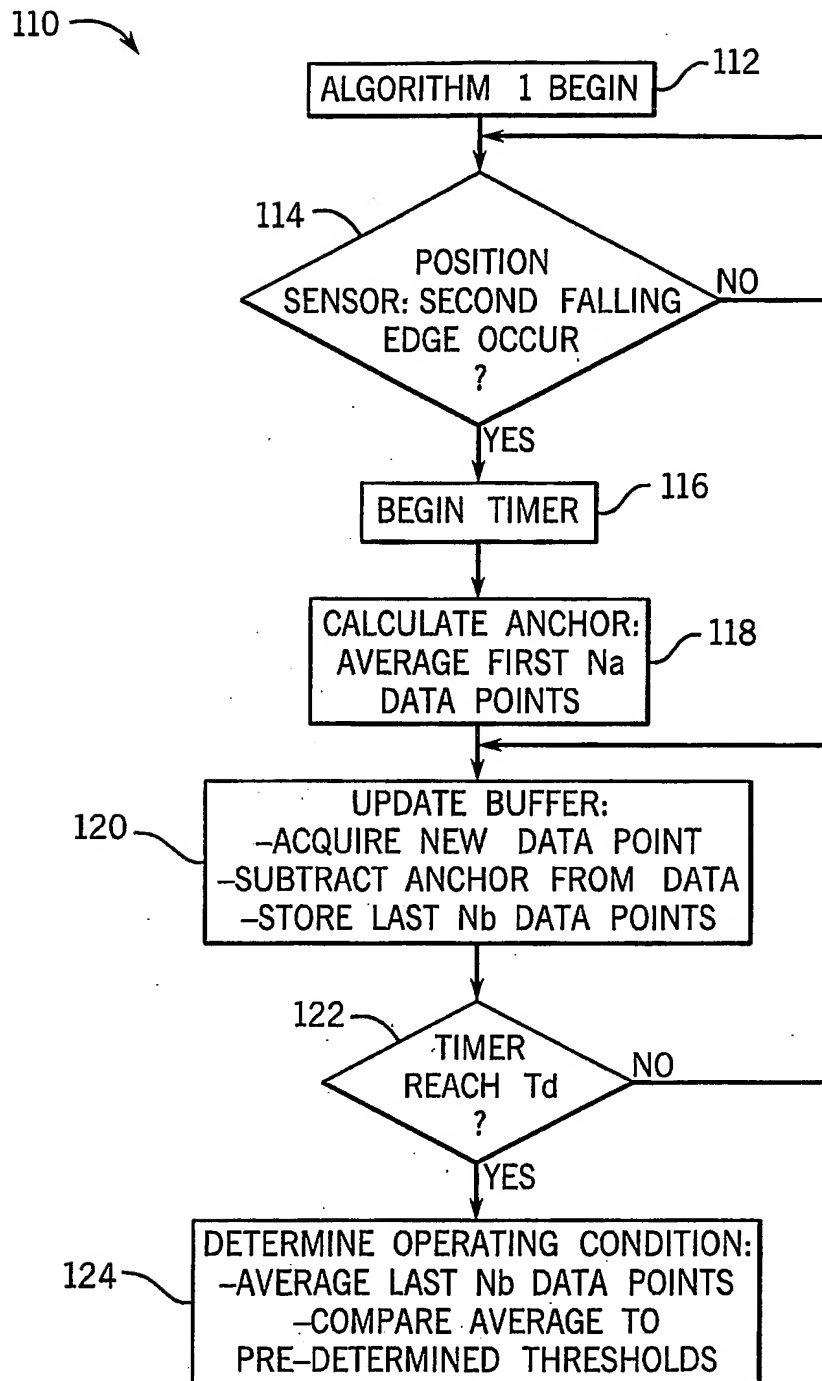


FIG. 4

5 / 7

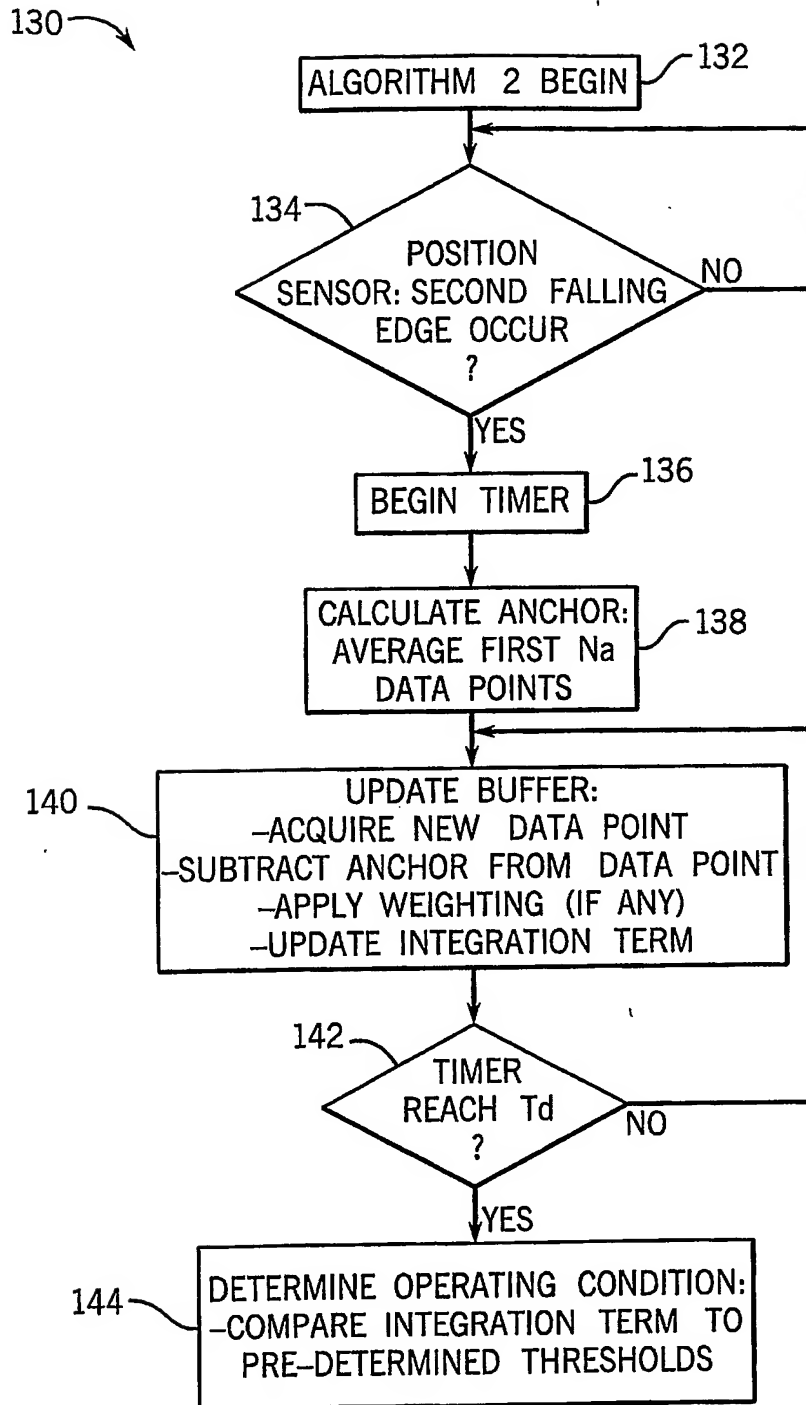


FIG. 5

6 / 7

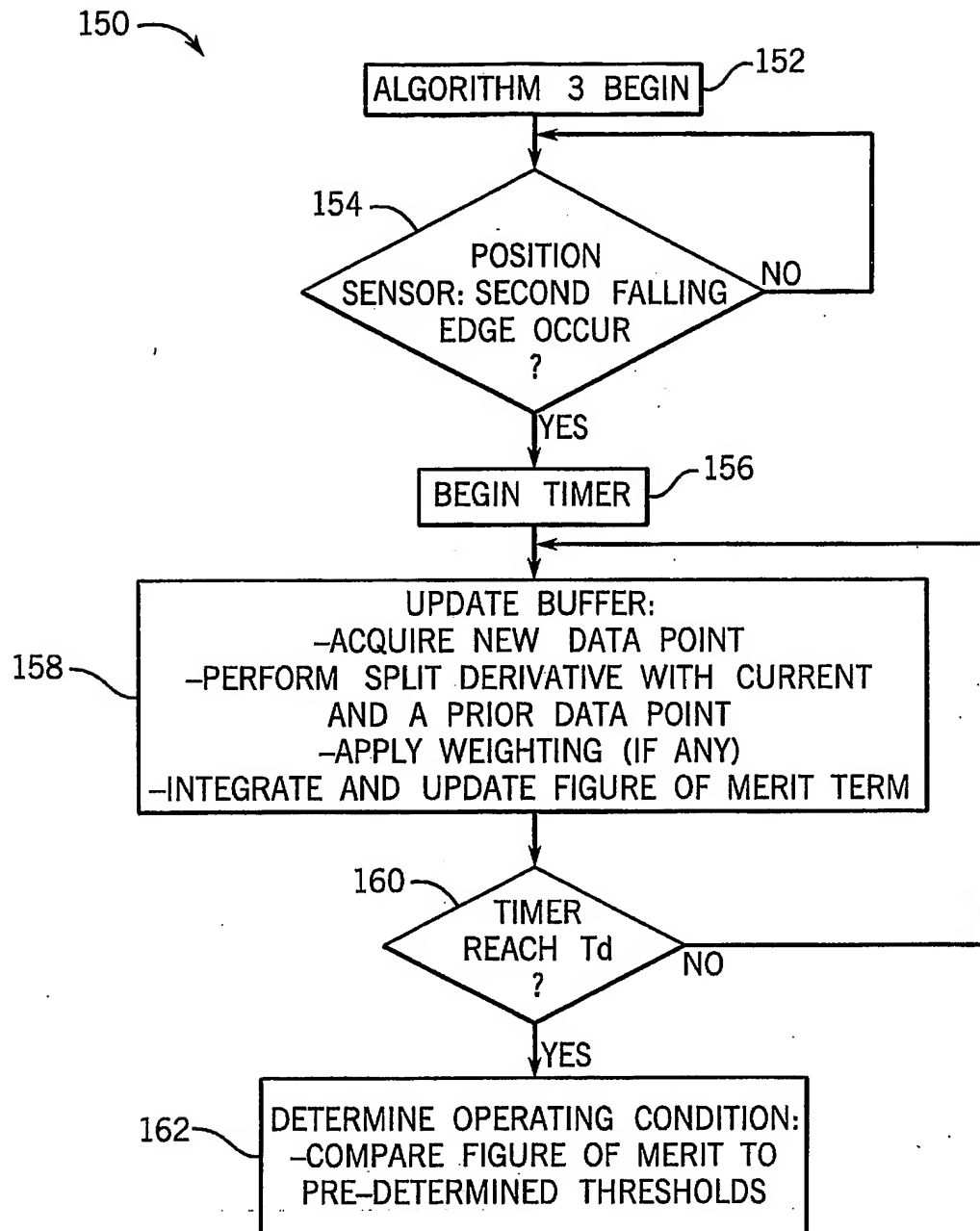


FIG. 6

7 / 7

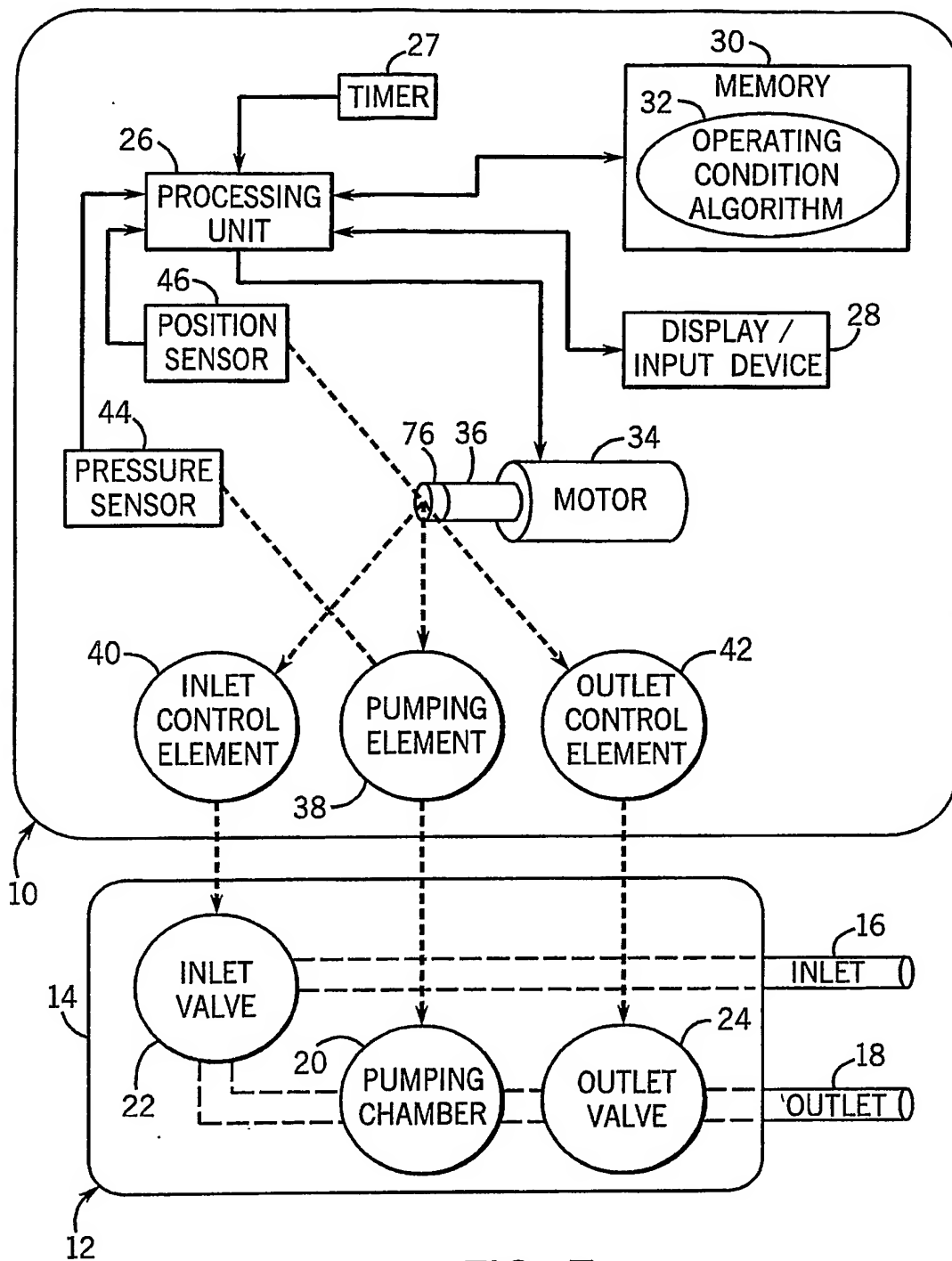


FIG. 7

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 03/31698

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M5/142

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M G06F F04B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, PAJ, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 464 392 A (COYNE HENRY ET AL) 7 November 1995 (1995-11-07)	1-4
A	column 27, line 56 -column 29, line 28; figures 18,23	5-23
X	US 5 554 013 A (ANDERSON CARL R ET AL) 10 September 1996 (1996-09-10)	1,2
A	column 8, line 9 - line 57	3-23
X	US 4 927 411 A (LAENEN EDWARD ET AL) 22 May 1990 (1990-05-22)	1,2
A	column 15, line 20 -column 16, line 4 column 4, line 59 -column 5, line 6; figure 25	3-23

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

Z document member of the same patent family

Date of the actual completion of the international search

9 February 2004

Date of mailing of the international search report

16/02/2004

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Michels, N

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int. Application No
PCT/US 03/31698

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5464392	A	07-11-1995	US 5304126 A	19-04-1994
			US 5100380 A	31-03-1992
			US 4696671 A	29-09-1987
			US RE36871 E	12-09-2000
			US 4828545 A	09-05-1989
			US 4865584 A	12-09-1989
			AU 592052 B2	04-01-1990
			AU 3856285 A	15-08-1985
			CA 1257165 A1	11-07-1989
			DE 3584450 D1	21-11-1991
			DE 3586596 D1	08-10-1992
			DE 3586596 T2	09-06-1993
			DE 3587826 D1	23-06-1994
			DE 3587826 T2	20-10-1994
			EP 0154191 A1	11-09-1985
			EP 0288716 A1	02-11-1988
			EP 0288717 A1	02-11-1988
			IE 850309 L	08-08-1985
			IL 74236 A	12-07-1990
			JP 1816304 C	18-01-1994
			JP 5024796 B	08-04-1993
			JP 60182961 A	18-09-1985
			JP 5237186 A	17-09-1993
			PT 79940 A	01-03-1985
			US 5108367 A	28-04-1992
US 5554013	A	10-09-1996	US 5302093 A	12-04-1994
			CA 2187756 A1	19-10-1995
			WO 9527852 A1	19-10-1995
			US 6110410 A	29-08-2000
US 4927411	A	22-05-1990	AU 618258 B2	19-12-1991
			AU 1531888 A	03-11-1988
			CA 1310873 C	01-12-1992
			CA 1323811 C2	02-11-1993
			CA 1324047 C2	09-11-1993
			DE 3876143 D1	07-01-1993
			DE 3876143 T2	22-04-1993
			DK 235888 A	02-11-1988
			EP 0293592 A2	07-12-1988
			ES 2036616 T3	01-06-1993
			GR 3006909 T3	30-06-1993
			JP 1005558 A	10-01-1989
			JP 2763005 B2	11-06-1998
			JP 2769460 B2	25-06-1998
			JP 10071202 A	17-03-1998